



# NORTH DAKOTA DEPARTMENT OF HEALTH

Division of Air Quality

## RADIOACTIVE MATERIAL LICENSING GUIDE

Licensing Guide for Mobile PET  
Service Providers

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## **Licensing Guide for Mobile PET Service Providers**

Certain North Dakota medical facilities have a North Dakota Radioactive Material License authorizing them to perform positron emission tomography (PET) with Fluorine-18 (F-18). This licensing guide is for mobile PET service providers who wish to become licensed to provide PET service at those facilities. (Note: This licensing guide does not address providing PET service at any medical facility that does not already have a North Dakota Radioactive Material License authorizing them to perform PET.)

1. Each PET mobile service van and camera must be separately licensed. Provide information on each PET mobile service van and camera to be licensed to operate in North Dakota.
2. A permanent in-state location for records retention must be provided. Secure week-end or off-service storage of the service van must also be provided. Access to records for inspection must be readily available during all normal business hours. Alternatively, complete records may be kept on the service van and no permanent in-state records location required if the department is provided a "24/7" location schedule with 48 hour advance notification for deviations or changes to the schedule. Describe how you will provide access to records for inspection by the ND Dept. of Health and provide security for the van and radioactive material.
3. Obtain a letter of authorization from each medical facility where service is to be provided, and provide a copy with the license application. The medical facility must have a radioactive materials license that authorizes PET and allows the presence of the transmission and calibration sources at their location of use. The mobile service license must also be amended for each new specific location of use, as they are added.
4. The RSO for the mobile service license must be immediately available by phone and physically present (on-site) within 2 hours of any significant incident involving the scanning van. Training and experience requirements for the RSO should be commensurate with use of sealed sources. At a minimum, this includes knowledge of packaging and transportation requirements; experience in the care and handling of sealed sources (inventories, leak tests, surveys, time/distance/shielding); operation and calibration of the PET camera, dose calibrator, and any survey instruments required. Provide the name of the RSO and describe their training and experience.
5. A camera operator/technologist must have a minimum of 2 days of PET work experience at a PET facility and be certified in nuclear medicine technology (CNMT or RT(N)). Confirm that all camera operators/technologists will meet this training and experience requirement.
6. Discuss who will perform patient injections.
7. Discuss with customers pertinent contract provisions which specify responsibilities for package receipt, dose preparation, patient injection, on-board holding areas, camera operation, patient release, waste disposal, source accountability, spill clean-up, and final release survey of the van. Provide specifics on these issues with the license application.
8. Describe all shielding for on-board dose storage, temporary waste receptacles, dose calibrator, patient waiting area, lavatory holding tank, etc.
9. Describe final survey procedures and documentation prior to departure of the van from a licensee's facility. Discuss actions in the event contamination is identified including emptying and rinsing of lavatory holding tank.

10. Request specific authorization to permanently store sealed sources overnight and on weekends in the scanning van. Provide a description of security procedures and restricted access and labeling of the van with a caution radioactive material sign (either inside or outside the van).
11. Provide procedures for dose calibrator checks and PET camera quality control (QC). Equipment QC and checks must be performed daily at each location of use before administering radioactive material.
12. Confirm that copies of the following documents will be maintained on the van at all times: location log, number of studies performed, source inventory, survey meter calibration, dose calibrator checks, camera QC, contamination surveys, radiological surveys, personnel dosimetry, personnel training records; personnel qualifications; shipping papers (to be kept accessible to the driver per transportation regulations).
13. For the transmission and calibration source(s) carried on the mobile PET scanning vehicle, provide information about the sources including the manufacturer, model number, radioactive material, activity, Sealed Source and Device Registry Number, number of sources, and total activity to be possessed.
14. Confirm that you will use only unit doses of PET radiopharmaceuticals.

#### AMENDING THE LICENSE

Applications for license amendments may be filed either on an application form or in letter form. The request should identify the license by number and should clearly describe the exact nature of the changes, additions or deletions. References to previously submitted information should identify the pertinent information by date, page and paragraph.

Amendment applications must be signed and dated. The original copy of the application should be submitted to the Department of Health and a copy should be maintained for your records.

License amendments must be accompanied by the appropriate license amendment fee as described in Chapter 33-10-11 of the North Dakota Radiological Health Rules. The amendment fee for this type of amendment is \$160; the annual fee is \$2200, check or money order made payable to the North Dakota Department of Health.